REMARKS

Interview request

Applicants also respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at 858 720 5133.

Status of the Claims

Pending claims

Claims 1 to 3, 6, 11 to 17, 20 to 22 and 50 to 62 are pending.

Claims added and canceled in the instant amendment

Claims 13 to 17 are canceled, without prejudice or disclaimer, and new claims 63 to 68 are added. Thus, after entry of the instant amendment, claims 1 to 3, 6, 11, 12, 20 to 22 and 50 to 68 will be pending and under consideration.

Allowable subject matter

Applicants thank the Examiner for noting that methods to recombinantly produce the polypeptide of SEQ ID NO:10 appear to be allowable over the prior art, and that claim 50 is only objected to as it depends on a rejected base claim; see page 18, paragraphs 25 and 26.

Outstanding Rejections

Claims 20, 21, 51 to 56 and 59 to 62, were rejected under 35 U.S.C. § 112, second paragraph. Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected under 35 U.S.C. § 112, first paragraph, written description requirement. Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected under 35 U.S.C. § 112, first paragraph, enablement requirement. Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Berka *et al.*, U.S. Patent No. 5,866,118, issued February 2, 1999, and filed March 18, 1997.

Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected on the ground of non-statutory obviousness-type double patenting for allegedly being unpatentable over claim 9 of

USPN 5,876,997. Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected on the ground of non-statutory obviousness-type double patenting for allegedly being unpatentable over claim 9 of USPN 6,190,897. Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected on the ground of non-statutory obviousness-type double patenting for allegedly being unpatentable over claims 13, 28, 29, 46, 81, 89 to 91, and 94 to 96, of co-pending US Pat App. Serial No. 09/777,566.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the amended claims. For example, support for claims directed to methods of expressing phytases comprising a homologous signal sequence or comprising a heterologous signal sequence in place of the homologous signal sequence, and in one aspect, comprising a sequence imparting a desired characteristic, can be found, *inter alia*, in paragraphs [0254], [0315] and [0316] of U.S. Patent Application Publication No. 20040091968 ("the '968 publication"). Support for claims directed to polynucleotides and polypeptides of the invention further comprising a coding and/or non-coding sequence can be found, *inter alia*, in at least paragraphs [0090] and [0140] of U.S. Pat. App. Publication No. 20040091968. Support for claims directed to methods of expressing phytases, wherein the phytase-encoding nucleic acids are within various expression and/or cloning systems, can be found, *inter alia*, in paragraphs [0283] and [0284] of the '968 publication. Support for claims directed to methods of expressing phytases in various yeast cells can be found, *inter alia*, in paragraph [0039] of the '968 publication. Accordingly, Applicants respectfully submit that no new matter is introduced by the instant amendment.

The Group Restriction Requirement, Election and Traversal

The Patent Office alleged that the pending claims of the application are directed to six separate and distinct inventions under 35 U.S.C. §121. In response, Applicants elected Group IV, including, *inter alia*, pending claims 1, 2, 20 to 22, 29, 50 (and new claims 51 to 58), drawn to, *inter alia* methods of recombinantly producing the polypeptide of SEQ ID NO:10, and classified

in, *inter alia*, class 435, subclass 69.1, with traverse. Applicants respectfully requested the Patent Office reconsider and, in part, withdraw the group restriction requirement for the reasons set forth in their previous response and amendment. In brief, Applicants respectfully submitted that all exemplary phytases sequences, including the phytase encoding nucleic acids SEQ ID NO:1 and SEQ ID NO:9, and the phytases SEQ ID NO:2 and SEQ ID NO:10, should be rejoined to a generic Group IV; in other words, Groups III and IV should be joined to a generic group drawn to methods for making a polypeptide having a phytase activity comprising, *inter alia*, expressing a phytase-encoding nucleic acid in a yeast. Thus, pursuant to 37 C.F.R. § 1.144, Applicants reserved the right to petition for review of the restriction requirement at any time prior to appeal.

Applicants thank the Examiner for acknowledging that claims 1 and 2 are generic linking claims and that Applicants are entitled to examination of these generic claims, and that the restriction requirement between the linked inventions is subject to the non-allowance of the linking claims 1, 2 and 51, see pages 2 to 3 of the OA.

Specification

The specification was objected to because of references to embedded hyperlinks and/or other forms of browser executable code, see paragraph 1, page 4, of the OA. The instant amendment addresses this issue.

Claim Objections

Claims 52, 54 and 56 are objected to for reasons set forth in paragraphs 5 and 6, page 5, of the OA. The instant amendment addresses this issue.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 20, 21, 51 to 56 and 59 to 62, were rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as discussed in paragraphs 7 to 14, on pages 5 to 7, of the OA. The instant amendment addresses this issue.

Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

New matter issues

The OA sets forth specific issues regarding claims 55 and 56 in paragraph 16, page 8, of the OA, noting that this is a new matter rejection. In particular, the Office alleges the term "peptide imparting a desired characteristic" is new matter. The instant amendment addresses this issue. Claim 55 in amended form it is drawn to "a sequence encoding an amino acid sequence comprising an N-terminal identification peptide imparting a desired characteristic":

> 55 (as amended). A method for making a recombinant phytase comprising: (a) ... , or the nucleic acid further comprises a sequence encoding an amino acid sequence comprising an N-terminal identification peptide imparting a desired characteristic; and the phytase-encoding nucleic acid comprises a sequence isolated from an *E. coli* bacterium; and (b)... .

The term "derived"

The OA sets forth specific issues regarding claims 1, 2, 20 to 22, 51, and 53 to 62 in paragraph 17, pages 8 to 10, of the OA. In particular, it is alleged, *inter alia*, that the specification fails to describe a representative number of species of the genus of phytases "derived" from a bacterium, as discussed in paragraph 17, on pages 8 to 10, of the OA. The instant amendment addresses this issue. The term "derived" has been deleted; for example, claims 1 and 55 in amended form read:

> Claim 1 (as amended): A method for making a polypeptide having a phytase activity comprising: providing a nucleic acid isolated from an *E. coli* bacteria encoding a polypeptide having a phytase activity; and ... .
>
> Claim 55 (as amended). A method for making a recombinant phytase comprising: (a) ... ; and the phytase-encoding nucleic acid comprises a sequence isolated from an *E. coli* bacterium; and (b)... .

Describing structures already well known in the art

The OA sets forth specific issues regarding claims 1, 2, 20 to 22, 51, and 53 to 62 in paragraph 17, pages 9 to 10, of the OA. In particular, it is alleged, *inter alia*, that the specification fails to describe a representative number of species of the genus of phytases including (1) specific amino acid fragments of SEQ ID NO:10 which are essential for any polypeptide comprising them to have phytase activity, (2) a correlation between structure and phytase activity, and (3) additional phytases (see, e.g., page 9, second full paragraph, of the OA).

The description need only describe in detail that which is new or not conventional. See Hybritech v. Monoclonal Antibodies, 802 F.2d at 1384, 231 USPQ at 94; Fonar Corp. v. General Electric Co., 107 F.3d at 1549, 41 USPQ2d at 1805 (source code description not required). This is equally true whether the claimed invention is directed to a product or a process. MPEP §2163, section II.A.3.(a), page 2100-179, 8th ed. Rev. 3, August 2005.

What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116; Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972). MPEP §2163, section II.A.3.(a), page 2100-180, 8th ed. Rev. 3, August 2005.

Applicants respectfully note that the claims are directed to method of using two types of phytases: first, phytases already known in the art; and second, the phytases having the sequences of SEQ ID NO:2 (encoded, e.g., by SEQ ID NO:1, described for the first time in this application's priority document, USSN 08/910,798, now US Patent No. 5,876,997) and SEQ ID NO:10 (encoded, e.g., by SEQ ID NO:9, described for the first time in this application's priority document, USSN 09/866,379, now US Patent No. 6,855,365). An example of a phytase already known in the art, is also described in this application's priority document, specifically the appA phytase from E. coli strain K12 (see Table 3 of USSN 09/580,515, now US Patent No. 6,720,014). The appA phytase was originally described as an acid phosphatase (Dassa, 1990, Journal of

Bacteriology, 172(9):5497-5500), but was later described as a phytase (Golovan, 2000, Canadian Journal of Microbiology, 46(1):59-71).

The description need only describe in detail that which is new or not conventional. Thus, with regard to use of known phytases in the methods of the invention, particularly in light of the fact that an exemplary known sequence is described in the specification, a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing.

The Office discusses University of California v. Eli Lilly & Co. However, the holding of this case only applies to written description issues for compositions claimed for the first time in the application at issue, not whether it would be necessary to describe in detail compositions already well known in the art to satisfy the written description requirement of section 112, first paragraph.

As noted above, in one aspect of the claimed methods, new phytases having the sequences of SEQ ID NO:2 (encoded, e.g. by SEQ ID NO:1) and SEQ ID NO:10 (encoded, e.g., by SEQ ID NO:9) are used.

Because the methods of the invention use only known phytases – with the exceptions of new phytases having the sequences of SEQ ID NO:2 (encoded, e.g. by SEQ ID NO:1) and SEQ ID NO:10 (encoded, e.g., by SEQ ID NO:9), which are described in complete detail in this specification, the skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, and the rejection under the written description requirement of section 112, first paragraph can be properly withdrawn.

Issues under 35 U.S.C. §112, first paragraph, enablement requirement

Claims 1, 2, 20 to 22, 51, and 53 to 62 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement, as set forth in paragraph 18, pages 10 to 13, of the OA.

The Patent Office states that the specification is enabling for a method to recombinantly produce the polypeptide of the invention SEQ ID NO:10. However, it is alleged that the

specification does not provide reasonable enablement to recombinantly produce any phytase. See, e.g., paragraph 18, first sentence, on page 10.

As noted above, Applicants respectfully note that the claims are directed to methods using two types of phytases: first, phytases already known in the art; and second, the phytases having the sequences of SEQ ID NO:2 (encoded, e.g., by SEQ ID NO:1, described for the first time in this application's priority document, USSN 08/910,798, now US Patent No. 5,876,997) and SEQ ID NO:10 (encoded, e.g., by SEQ ID NO:9, described for the first time in this application's priority document, USSN 09/866,379, now US Patent No. 6,855,365). An example of a phytase already known in the art, is also described in this application's priority document, specifically the appA phytase from E. coli strain K12 (see Table 3 of USSN 09/580,515, now US Patent No. 6,720,014).

A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). MPEP §2164.01, pages 2100-193, 8th ed. Rev. 3, August 2005. The law does not require that Applicants teach any more than is in their specification in order to satisfy the requirements of 35 U.S.C. §112, first paragraph.

The Office discusses In re Wands. However, the holding of this case only applies to enablement issues for compositions claimed for the first time in the application at issue, not whether it would be necessary to describe in detail compositions already well known in the art to satisfy the enablement requirement of section 112, first paragraph. See, e.g., MPEP §2164.06(b), page 2100-203, 8th ed. Rev. 3, August 2005.

Because the methods of the invention use only known phytases – with the exception of the new phytases having the sequences of SEQ ID NO:2 (encoded, e.g. by SEQ ID NO:1) and SEQ ID NO:10 (encoded, e.g., by SEQ ID NO:9), which are described in complete detail in this specification, and the skilled artisan at the time of the invention could have made known phytases recombinantly without undue experimentation, the instant specification sufficiently enabled the

skilled artisan to make and use the invention, and the rejection under the enablement requirement of section 112, first paragraph can be properly withdrawn.

Issues Under 35 U.S.C. § 102(e)

Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Berka *et al.*, U.S. Patent No. 5,866,118, issued February 2, 1999, and filed March 18, 1997 (hereinafter "Berka"). The filing date of the earliest priority document for this application is August 13, 1997 (for USSN 08/910,798).

The legal standard for anticipation under 35 U.S.C. §102 is one of strict identity. To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention. In re Paulson, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994)(citing In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP §2131; pg 2100-76, 8th ed., Rev. 3, August 2005.

As noted by the Office, Berka discloses cloning and recombinant expression of a phytase from the filamentous fungus *Thennomyces lanuginosus*. After entry of the instant amendment, claimed methods of this invention will be limited to use of phytase-encoding nucleic acid isolated from an *E. coli* bacteria. Thus, because Berka is not a single prior source which contains each and every limitation of the claimed invention, the rejection under section 102 can be properly withdrawn.

Double Patenting Issues

USPN 5,876,997

Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected on the ground of non-statutory obviousness-type double patenting for allegedly being unpatentable over claim 9 of USPN 5,876,997, for reasons set forth in detail in paragraph 22, pages 15 to 16, of the OA.

The terminal disclaimer submitted herein should address this issue.

USPN 6,190,897

Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected on the ground of non-statutory obviousness-type double patenting for allegedly being unpatentable over claim 9 of USPN 6,190,897, for reasons set forth in detail in paragraph 23, pages 16 to 17, of the OA.

The terminal disclaimer submitted herein should address this issue.

US Pat App. Serial No. 09/777,566

Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected on the ground of non-statutory obviousness-type double patenting for allegedly being unpatentable over claims 13, 28, 29, 46, 81, 89 to 91, and 94 to 96, of co-pending US Pat App. Serial No. 09/777,566, for reasons set forth in detail in paragraph 24, pages 17 to 18, of the OA.

The terminal disclaimer submitted herein should address this issue.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §112, first and second paragraphs, and 35 U.S.C. §102(e); and in light of the terminal disclaimer submitted herein, all rejections based on non-statutory obviousness-type double patenting. In view of the above, claims in this application after entry of the instant amendment are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **docket No. 564462001824**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at 858.720.5133.

Dated: October 27, 2006

Respectfully submitted,

By _____

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